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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
08/937,443	09/25/97	RENIRIE	A P-4782

Section 1.01

On this application is shown
MEDTRONIC INC
7000 CENTRAL AVE NE
MINNEAPOLIS MN 55432

0M41/0427

EXAMINER
EVANISKO, G

ART UNIT	PAPER NUMBER
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3737

DATE MAILED 04/27/99

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.
08/937,443

Applicant(s)
Renirie et al

Examiner
George Evanisko

Group Art Unit
3737



☒ Responsive to communication(s) filed on Mar 16, 1999

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 1-36 is/are pending in the application.

Of the above, claim(s) 3, 4, 12, 13, 16, 17, 20, 21, 27, 28, and 33 is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 1, 2, 5-11, 14, 15, 18, 19, 22-26, 29-32, and 34-36 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☒ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 2

☐ Interview Summary, PTO-413

☒ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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DETAILED ACTION

Election/Restriction

1. Claims 3, 4, 12, 13, 16, 17, 20, 21, 27, 28, and 33 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b) as being drawn to non-elected species. Election was made **without** traverse in Paper No. 7. Although, paper 7 states that claims 1-36 read on the elected species of inspiration and expiration, claims 3, 4, 12, 13, 20, 21, and 28 do not read on that species, since the embodiments dealing with inspiration only and expiration only are not generic to the species of inspiration and expiration. In addition, the election of species dealing with the use of the different amplitude means to control the stimulation has been withdrawn since, as described in the specification and shown in figure 5, each one of the amplitude means can be used independently and together to control the stimulation.

Specification

2. The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: The use of “ventricular work output” and “cyclical ventricular work output” in claim 36 has not been used in the specification. The abstract and specification (on page 17) uses “ventricular power output” or something similar to “power output” when referring to the

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calculation of "work". The examiner has interpreted claim 36 as using the "work" output (from page 17) as a basis for controlling the pacing rate.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claim 36 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The subject matter not described in the specification is the use of ventricular work output by itself to control the pacing means. Essential subject matter relating to the respiration sensor to determine the respiration cycle for use in the pacing means or control means is critical to the practice of the invention but is missing from the claim. As shown in figure 5 and described on page 19, the work output is sent to the rate modulator where an algorithm processes the output and sends the processed output to the rate control. But, the rate control also receives information on the respiration cycle as stated on page 19, lines 11 and 12, for "timing the change in rate...as a function of the respiration information." Also, on page 22, lines 5-7, "the system tracks patient respiration, and increases rate during inspiration relative to expiration, so as to lessen changes in ventricular cyclical power output."

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Therefore, the subject matter relating to controlling the patients heart by using only ventricular work output was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 1, 2, 5-11, 14, 15, 18, 19, 22-26, 29-32, and 34-36 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claims 1 and 18, "the pacing rate" lacks antecedent basis (it is suggested to use "a pacing rate").

In claim 1, "so as" is vague since it is unclear whether this is a limitation of the claim or a result of the modulation means. The examiner has interpreted the claim as containing the limitations after "so as". In the claim, "the patient's inspiration phase" and "the patient's expiration phase" is vague and inferentially included since the respiration means has not been given a function to determine these phases.

In claim 5, "the amplitude of pacing rate change" lacks antecedent basis; "said patient's respiratory cycle" lacks antecedent basis.

In claims 7 and 8, "said patient's ventricles" lacks antecedent basis.

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In claim 9, "the change of rate amplitude" lacks antecedent basis since "the amplitude or pacing rate change" has been used in claim 5; "a respiratory cycle" is vague since it has been used in claim 5. Is this the same respiratory cycle?

In claims 10 and 11, "said rate amplitude change" lacks antecedent basis.

In claim 14, "patient rate" lacks antecedent basis.

In claim 18, "said patient's respiration" lacks antecedent basis.

In claims 21, 23, 24 and 25, "comprising" should be "further comprising" since structure is being added to the system.

In claim 23, "or" is vague since it is alternative language.

In claim 26, "so as" is vague.

In claim 30, "the rate" lacks antecedent basis; "to periods of expiration" makes the claim incomplete since the respiration means has not been given a function to determine periods of expiration.

In claim 31, "said phasic rate controlled pulses" lacks antecedent basis; "so as" is vague; "the said" should be "said".

In claims 32, 34, and 35, "comprising" should be "further comprising the steps of" since the claims contain additional steps to the method.

In claim 36, "the patient's cyclical ventricular work output" lacks antecedent basis ("ventricular work output" is used in the preamble); "so as" is vague; the claim is incomplete for omitting cooperative relationship between elements for not relating the control means to the

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variation means for the control means to receive the variation signal for controlling the rate. The claim is incomplete for omitting essential elements, such omission amounting to a gap between the elements for not having the system contain a respiration means to adjust the pacing rate due to the respiration.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

8. Claims 1, 2, 5, 9, 18, 19, 26, and 29-32 are rejected under 35 U.S.C. 102(e) as being anticipated by Ekwall (EP 0753324). Ekwall states in the first full paragraph of column 6, that the change in the stimulation energy can be achieved by increasing the number of pulses in a stimulation and to vary their number and/or amplitude and/or duration and/or timing. Since Ekwall increases the stimulation energy during inhalation, the number of pulses produced during inhalation will be increased in his system when using his method of changing the stimulation energy by varying the number of pulses. In addition, since Ekwall's system can set a maximum amplitude for the pulses at given stages in the respiratory cycle, his system will be able to limit the maximum rate of amplitude change.

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Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

10. Claim 15 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ekwall.

Ekwall discloses the claimed invention of delivering pacing pulses to the heart except for delivering the pacing pulses specifically to the atrium. It would have been obvious to one skilled in the art to deliver pacing pulses to the atrium to stimulate the heart, since applicant has not disclosed that delivering pacing pulses to the atrium provides any criticality and/or unexpected results and it appears that the invention would perform equally well with delivering pacing pulses to any part of the heart.

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Allowable Subject Matter

11. Claims 6-8, 10, 11, 14, 22-25, 34 and 35 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

12. Since allowable subject matter has been indicated, applicant is encouraged to submit formal drawings in response to this Office action. The early submission of formal drawings will permit the Office to review the drawings for acceptability and to resolve any informalities remaining therein before the application is passed to issue. This will avoid possible delays in the issue process.


Conclusion

13. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to George Evanisko whose telephone number is (703) 308-2612.

GRE

April 21, 1999


George R. Evanisko
Patent Examiner